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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,471	11/08/1999	DENISE R. COOPER	114205.1200	5279

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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/435,471

Applicant(s)

COOPER ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7 and 19-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-38 and 42-47 is/are allowed.
- 6) ☒ Claim(s) 1,3-7, 19-29, 39 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1003. 6) ☐ Other:

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### DETAILED ACTION

The amendment filed October 6, 2003 has been entered. Claims 21, 23, 39, and 41 have been amended. Claim 2 has been cancelled.

Accordingly, Claims 1, 3-7 and 19-47 remain pending in the instant application.

The following rejections are reiterated and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-7, and 19-29 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 5-6 of the Office Action of Paper No. 29 (mailed 12/17/02) and on pages 2-4 of the Office Action of Paper No. 34 (mailed 7/30/03), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants are referred to the final guidelines on written description published January 5, 2001 in the Federal Register at Volume 66, Number 4, pp. 1099-1111 (also available at [www.uspto.gov](http://www.uspto.gov)).

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of ‘written description’ inquiry, whatever is claimed” (see

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page 1117). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision.

A genetic element is a chemical compound, albeit a complex one, and it is well-established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. See *Oka* 849 F.2d at 583, 7 USPQ2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.* an element that functions in a manner similar to the carbohydrate responsive mRNA instability element disclosed in the instant specification, because an alleged conception having no more specificity than that is simply **a wish to know the identity of any material with that biological property**. The court held that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.* until after the gene has been isolated. *Amgen v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

The claims are directed to constructs encoding mRNA comprising a carbohydrate responsive mRNA instability element, vectors comprising the construct, host cells comprising the construct, primers that bind to the carbohydrate responsive mRNA instability element, and methods of using the construct. The claims cover any carbohydrate responsive mRNA instability element, and thereby any element that functions in the manner disclosed in the specification. However, the specification describes only a single carbohydrate responsive mRNA instability element. The specification fails to describe the genus of carbohydrate responsive mRNA instability elements as claimed. The specification does not describe a representative number of species of genetic elements that would constitute a "carbohydrate responsive mRNA instability element." Thus, one of skill in the art could not envision the entire genus of

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“carbohydrate responsive mRNA instability elements” as claimed and consequently the written description requirement has not been met. The specification does not teach what distinguishing features are shared by members of this genus. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only a single “carbohydrate responsive mRNA instability element” is described by its complete structure. Next then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. In this case, no other species have been described by other relevant identifying characteristics. This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the entire genus of genetic elements covered by the claims, at the time the application was filed. Thus, it is concluded that the written description requirement is not satisfied for the claimed constructs, vectors, host cells, primers, and methods.

At page 8 of the response, Applicants argue that the specification does provide a sufficient written description of the genus of carbohydrate responsive mRNA instability elements because SEQ ID NO: 9 is provided as an exemplified carbohydrate responsive mRNA instability element and because one of skill in the art can readily determine other homologous nucleic acid sequences that function as carbohydrate responsive mRNA instability elements, based upon sequence similarity. Applicants point to Exhibit A which provides a sequence comparison showing that SEQ ID NO: 9 is highly conserved across species. However, there is nothing in the claims that requires homology or sequence similarity to the exemplified SEQ ID NO: 9. On the contrary, the claims cover structurally divergent nucleic acid elements that function in a manner similar to the disclosed element. Furthermore, no common structural feature is disclosed in the specification or recited in the claims to provide for a relevant identifying characteristic. Thus, it is concluded that the specification does not provide a written description of the entire genus of genetic elements covered by the claims.

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*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 23, 39, and 41 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

Patent No. 5,795,961 (Wallace et al.).

The claims have been amended so that they now recite the limitation “hybridizing to at least 15 consecutive bases” of a nucleotide sequence or polynucleotide.

As discussed in the previous Office Action, Wallace et al. disclose SEQ ID NO:5, a 37 nucleotide sequence that would hybridize to SEQ ID NO: 9 of the instant application, as well as a polynucleotide comprising SEQ ID NO: 9. See the sequence alignment provided with the Office Action of 7/30/03. The nucleic acid of Wallace et al. could be used as either a primer or a probe.

At page 9 of the response, Applicants assert that it is evident from the sequence alignment that SEQ ID NO: 5 of Wallace et al. does not contain 15 consecutive bases that hybridize with SEQ ID NO: 9 of the subject invention. On the contrary, first it is noted that the nucleic acid of Wallace et al. is 37 nucleotides in length and the entire nucleic acid will hybridize to any nucleic acid comprising SEQ ID NO: 9, regardless of the length of the nucleic acid comprising SEQ ID NO: 9. Second it is noted that the claim language does not require that the nucleic acid claimed must contain 15 consecutive bases that hybridize with SEQ ID NO: 9 as Applicants argue, but rather requires that the claimed nucleic acid hybridize to at least 15 consecutive bases of “a nucleotide sequence encoding a carbohydrate responsive mRNA instability element; and indeed the nucleic acid disclosed by Wallace et al. hybridizes to a segment of the subject “nucleotide sequence” over at least 26 consecutive bases.

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Thus, the claimed invention is disclosed in the prior art.

*Conclusion*

Claims 30-38, 40, and 42-47 are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The central official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to William Phillips, whose telephone number is (703) 305-3482.

Art Unit 1632 will be moving to the new USPTO headquarters on January 13, 2004. After that date, Examiner Falk can be reached at (571) 272-0728 and Examiner Reynolds can be reached at (571) 272-0734.

Anne-Marie Falk, Ph.D.

*Anne-Marie Falk*  
**ANNE-MARIE FALK, PH.D**  
**PRIMARY EXAMINER**